REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

It is acknowledged that the foregoing amendments are submitted after final rejection. However, because the amendments do not introduce new matter or raise new issues, and because the amendments either place the application in condition for allowance or at least in better condition for appeal, entry thereof by the Examiner is respectfully requested.

I. Status of the Claims

Claims 1-7, 15-19 and 21-28 were pending and under active consideration in the subject application. Claims 1-7 and 23 have been withdrawn from consideration. With this submission claims 24, 26, and 27 have been amended, no claims have been canceled and no claims have been newly added. Hence, upon entry of this paper, claims 1-7, 15-19 and 21-28 will remain pending. Additionally, claims 15-19, 21, 22, and 24-28 will remain under active consideration. Support for the claim amendments can be found throughout the specification.

A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

II. Rejections Withdrawn

Applicants wish to thank the Examiner for withdrawing the rejections of claims 24-28 under 35 U.S.C. §112 first paragraph.

III. 35 U.S.C. §112 Rejection

Claims 26 and 27 are rejected under 35 U.S.C. §112 as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner alleges that claims 26 and 27 of the claimed invention are indefinite for reciting the term "gene."

To expedite prosecution and without acquiescing to the propriety of the rejection, applicants have deleted the term "encoded by the gene" and "the gene encoding" from claims 26 and 27 respectively, which should render the rejection moot. As such applicants respectfully request withdrawal of the rejection.

IV. 35 U.S.C. §102 Rejection

Claims 15-19, 21, and 22 are rejected under 35 U.S.C. §102 as allegedly anticipated by Morin. The Office has considered the declaration filed on July 14, 2009 under 37 CFR 1.132 and found that the declaration is insufficient to overcome the current rejection. Specifically, the Office argues that the declaration is directed to the operability of the prior art and the use of the anti-HM1.24 antibody. However, the Office argues that the instant claims are drawn to the use of any antibody that binds to SEQ ID No.2, and not only the specific HM1.24 antibody. Applicants respectfully traverse this rejection.

A. The Current Inherency and Anticipation Standard

If the Examiner infers the presence of a particular element based on inherency, in order for such an inherency-type rejection to be sustained, the inferred element must necessarily result. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955 (Fed. Cir. 1993); *In re Oelrich*, 666 F.2d 568, 581, 212 USPQ 323 (CCPA 1981). The Examiner's attention is further drawn to MPEP §2112 which states that the Examiner has the burden to show a basis in fact and/or technical reasoning to support his or her determination that an allegedly inherent characteristic necessarily flows from the teaching of the applied reference. *Ex parte Levy*, 17 USPQ2d 1461, 1464 (BPAI 1990)

A claim in a patent application is anticipated (*i.e.* , lacks novelty) if all of its elements are present in a **single** reference in the prior art. Thus, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California,* 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

B. Morin Does Not Teach Each and Every Element of the Claimed Invention

Applicants' claimed invention is directed towards a therapeutic method for solid tumors comprising administration of an antibody that specifically binds to SEQ ID NO: 2 and has ADCC activity. Morin clearly does not teach an antibody that has antibody dependent cell mediated cytotoxicity (ADCC). However, the Office has previously argued that "antibody dependent cell mediated cytotoxicity (ADCC) is an inherent property of an antibody, particularly an IgG antibody." (Office Action dated May 7, 2008, page 5) This assumption is incorrect for at least two reasons.

First, US Patent No. 7,592,005 ("the '005 patent") issued to Tahara describes an anti-BST-2 antibody which is exemplified by the "b-76-8 antibody." As shown in Table 1, the b-76-8 antibody is of the subclass IgG1. Example 19 of the '005 patent shows that the b-76-8 antibody does not induce cell damaging activity. Specifically, the '005 patent states "**when the control human IgG1 and the b-76-8 antibody were added to the IM9 cells, no significant cell damaging activity was observed**. In the case of May-b-76-8 antibody, cellular cytotoxicity was observed depending on its concentration" ('005 patent, column 20, lines 14-17). The May-b-76-8 antibody is Maytansine-conjugated b-76-8 antibody, where the Maytansine is an anti-cancer chemotherapeutic agent. Thus, in contrast to the b-76-8 antibody, the May-b-76-8 antibody exhibits cell damaging activity. As such, it is clear that ADCC is not an inherent property of all anti-BST2 antibodies.

Second, the Morin reference itself admits that not all antibodies molecules exhibit antibody dependent cell mediated cytotoxicity. Specifically, Morin states

> The tumor marker genes of the invention can be employed as therapeutic targets for the treatment or prevention of ovarian cancer. For example, an antibody molecule that specifically binds a cell surface-localized ovarian tumor marker polypeptide can be **conjugated to a radioisotope or other toxic compound**. Antibody conjugates are administered to the subject such that the binding of the antibody to its cognate ovarian tumor marker polypeptide results in the **targeted delivery of the therapeutic compound** to ovarian tumor cells, thereby treating an ovarian cancer.

(emphasis added) (Morin at paragraph [0072]). As such, Morin teaches that an antibody is conjugated to a therapeutic compound, such as a radioisotope or other toxic compound.

Thus, the antibody *per se* functions for targeting. In contrast, the anti-ovarian cancer effect is provided by the therapeutic compound, i.e. "a radioisotope or other toxic compound."

If the antibody per se of Morin exhibited antibody dependent cell mediated cytotoxicity, its conjugation with the therapeutic compound would be unnecessary. Therefore, it is clear from the description cited by the Examiner, that the antibody described in Morin does not inherently exhibit "antibody dependent cell mediated cytotoxicity."

For at least these reasons Applicants respectfully request that the 35 U.S.C. § 102 rejection be withdrawn.

CONCLUSION

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing or a credit card payment form being unsigned, providing incorrect information resulting in a rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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